REMARKS

Status of the Claims

The pending Office Action addresses claims 7-11 and 13-26. Claims 20-26 are allowed. Claims 7-11, 13-15, 17 and 19 stand rejected. Claims 16 and 18 are objected to. Applicant has amended claim 7 to incorporate the recitations of claim 8, which is now canceled. Dependent claims have been amended only to correct their dependencies. No new matter is added.

Allowable Subject Matter

The Examiner states:

> Claims 16 and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
>
> Claims 20-26 are allowed.
>
> The indicated allowability of claims 9-11, 14-15, 17 and 19 is withdrawn in view of the newly discovered reference(s) to Zdeblick et al. (6,595,995), Pasquet et al. (U.S. 6,716,245), and Lin (U.S. Patent No. 6,569,168). Rejections based on the newly cited reference(s) follow.

In fact, as is shown in the sections below, the newly discovered references are wholly irrelevant to the claimed invention. Accordingly, Applicant traverses the newly made (some 8 years into prosecution of this application) rejections over never before cited references.

The Invention

The present invention is directed to a device, system, and method useful for implanting a prosthesis, such as an artificial intervertebral disc, within a patient in a safe and efficient manner. In particular, the invention provides a device, system, and method for aligning an imaging device (an x-ray machine for example) with a spinal disc prosthesis so that a doctor can image the prosthesis (by taking an x-ray image for example) to confirm correct placement of the prosthesis with a single image.

To fully understand the claimed invention, it is first necessary to appreciate the state-of the art at the time of the Applicant's invention, which represents the background against which the claimed invention was developed.

The Problem Addressed by the Invention is the Inefficient Verification of Prosthesis Placement

Following the removal of an diseased or damaged spinal disc, an artificial disc can often be implanted in the resulting space between to two vertebrae so as to maintain the spatial and functional physiological integrity of the spinal column. In order to maintain the natural load bearing and kinematic characteristics of the patient's spine, most spinal implants incorporate either lordotic or kyphotic angles, and a slight rotation of the implant during implantation about the local axis of the spine can cause misalignment of the desired angles significantly affecting the ability to restore lordosis or kyphosis and the desired spinal load transfer and kinematics. (Page 1, lines 28-32.) Thus, in order to prevent misalignment during a disc replacement procedure, an image obtaining device, such as an X-ray machine, is brought into the operating room (typically mounted on a C-arm) in order to image the implanted prosthesis to determine whether it is properly placed within a patient. (Page 1, line 32 - page 2, line 4.)

A key step in obtaining images that can tell the surgeon whether the implant is properly aligned within the patient is to properly align the imaging device itself. (Page 2, lines 6-7.) Many times, this is done in the operating room simply by inserting the prosthetic disc, checking the angular orientation of the disc by visually determining whether an implant inserter tool connected to the disc is extending straight up from the operating table or is relatively aligned with respect to anatomical landmarks, moving the C-arm into position so that the X-ray or other imaging device is directly over the disc, and taking an X-ray or other image. (Page 2, lines 7-13.) If upon viewing the image, the imaging device is not properly aligned for making the needed determination, its position is adjusted and a new image is obtained. (Page 2, lines 13-14.)

This process of aligning the imaging device may be required yet again if the implant is not correctly aligned and adjustment of the implant and further implant orientation verification is required, subjecting the patient to multiple x-ray attempts as well as a lengthy procedure. (Page 2, lines 14-17.)

For well known reasons, it is preferable to minimize the patients exposure to x-rays and it would be desirable to take as few x-rays as possible during the procedure. (Page 2, lines 17-19.) In addition, it is also preferable to minimize the amount of time for the overall procedure, and thus reduce the patients exposure to anesthesia. (Page 2, lines 19-20.) Hence, it is desirable to minimize the time duration involved in the imaging verification step. (Page 2, lines 20-21.)

The Invention Solves the Problem by Providing an Alignment Guide for Verifying the Orientation of an Image Taking Device with Respect to the Prosthesis, and a System and Method for Its Use

The claimed invention allows more efficient verification of the placement of an image obtaining device with respect to a surgical implant, especially a spinal disc implant, during the implantation procedure. FIG. 1 of the application, reproduced below, shows an overall system view illustrating the alignment verification device 10 engaged to a prosthesis 102 that has been implanted in the patient's 120 spine. The alignment verification device lOis being used in the Figure to correctly align an image obtaining device 106, such as an x-ray, with the prosthetic device 102. (Page 5, lines 22-24.) The image obtaining device 106 is generally mounted on a structure 100, such as a C-arrn, to allow the image obtaining device 106 to be moved around the operating room and to be oriented as desired. (Page 5, lines 26-28.) In addition, image obtaining device 106 typically includes a sighting element 108, such as a laser pointer, for providing a visual indication as to the aiming or orientation of the image obtaining device. (Page 5, lines 28-31.) This allows the image obtaining device 106 to be correctly oriented before the image is taken, thus insuring that only one image will be necessary to determine whether the prosthesis has been properly implanted.

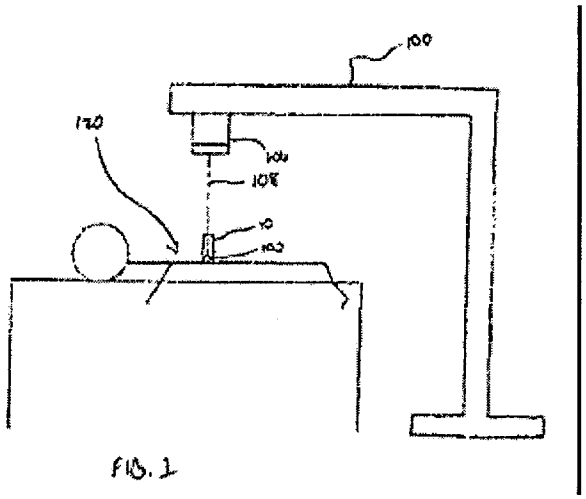

FIG. 1

The alignment verification device 10, shown in Applicant's FIG. 2 (reproduced below) along with a prosthesis 102 to which it is engaged, includes a spacer element 12 having two elongate members 14, 16, and an alignment guide surface 40 defining an alignment orifice 42. (Page 6, lines 2-4.) The spacer element 12 has an insert engaging element 20 on its distal end which includes individual prosthesis engaging elements 22, 24 on a distal end of each of the elongate members 14, 16, respectively. (Page 6, lines 4-6.) Insert engaging element 20 (via the individual prosthesis engaging elements 22, 24) interacts with prosthesis 102 to place the alignment orifice 42 into a predetermined geometric relationship with, and spaced apart from, the prosthesis 102 so that sighting element 108 can be aimed through alignment orifice 42 to strike a predetermined visual indicator point 26 to provide a visual indication that image obtaining device 106 (shown in FIG. 1) has been placed in a known orientation with respect to prosthesis 102, allowing verification of the orientation of the prosthesis to proceed efficiently, generally with a single image verifying the placement of the prosthesis. (Page 6, lines 6-12.)

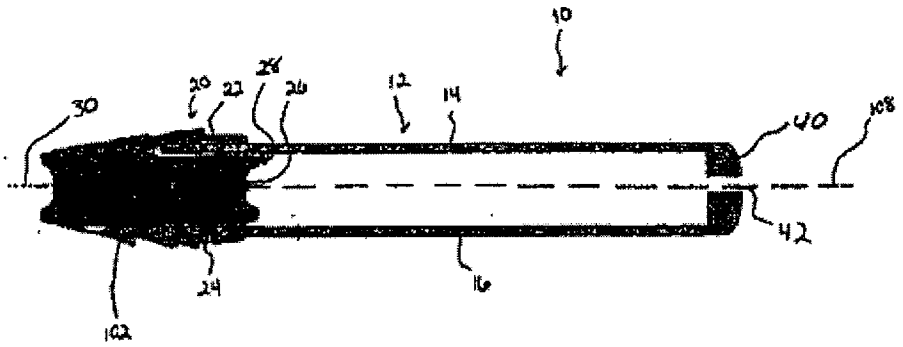

FIG. 2

The Invention as Claimed in the Rejected Independent Claims

There are two rejected independent claims (7 and 19, both rejected as anticipated) – independent claim 22 is allowed.

Independent Claim 7 Recites a Prosthesis Verification System That Includes the Alignment Verification Device and the Spinal Disc Prosthesis

Applicant's claim 7 recites a prosthesis alignment verification system that includes an alignment verification device 10 and a spinal disc prosthesis 102. The alignment verification device 10 has a spacer element 12 having a prosthesis engaging element 22, 24 disposed on its distal portion. An alignment guide surface 40 is affixed to the spacer element 12 and defines an alignment orifice 42; the alignment orifice 42 is spaced apart from the prosthesis engaging element 22, 24. The spinal disc prosthesis 102 has an engaging element 50, 70 and a visual indicator element 26. The engaging element 50, 70 is configured to releasably engage the prosthesis engaging element 22, 24 of the alignment verification device 10 so that, upon engagement, the alignment orifice 42 is spaced apart from the visual indicator element 26. Further, the engagement of the alignment verification device 10 with the spinal disc prosthesis 102 is adapted to permit a sighting element 108 of an image obtaining device 106 to be aligned with the alignment orifice 42 and the visual indicator element 26 so that an image obtaining device 106 is aligned with the spinal disc prosthesis 102 in a known orientation.

Independent Claim 19 Recites a Verification Method That Verifies the Orientation of the Image Obtaining Device With Respect to the Prosthesis Using the Alignment Verification Device

Applicant's claim 19 teaches a method for verifying the orientation of an image obtaining device 106 with respect to an implanted prosthesis 102 that includes providing an alignment verification device 10, and engaging the alignment verification device 10 to the implanted prosthesis 102. The alignment verification device 10 has a spacer element 12 with a prosthesis engaging element 22, 24 disposed on its distal portion. An alignment guide surface 4Q is affixed thereto and defines an alignment orifice 42 that is spaced apart from the prosthesis engaging element 22, 24. The prosthesis 102 has an engaging element 50, 70 and a visual indicator element 26, and the engaging element 50, 70 is configured to releasably engage the prosthesis engaging element 22, 24 of the alignment verification device 10 so that, upon engagement, the alignment orifice 42 is spaced apart from the visual indicator element 26. Further, the method includes orienting the imaging obtaining device 106 so that a sighting element 108 on the image obtaining device 106 is aimed through the alignment orifice 42 to the visual indicator element 26 to provide a visual indication that a predetermined orientation between the image obtaining device 106 and the prosthesis 102 has been achieved.

Rejections Pursuant to 35 U.S.C. § 102(e)

The Examiner rejects claims 7-8, 13, 17 and 19 pursuant to 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,595,995 (Zdeblick). Specifically, the Examiner states:

> Zdeblick et al. disclose a prosthesis alignment verification system, comprising an alignment verification device (see FIG. 21) including a spacer element (ref. #245) having proximal and distal portions and a prosthesis engaging element disposed on the distal portion; and an alignment guide surface (ref. #170/171) affixed to the spacer element and defining an alignment orifice (ref. #180), the alignment orifice being spaced apart from the prosthesis engaging element; and a spinal disc prosthesis (ref. #240) having an engaging element and a visual indicator element (surface of bone dowel ref. #240), the engaging element configured to releasably engage the prosthesis engaging element of the alignment verification device so that, upon engagement, the alignment orifice is spaced apart from the visual indicator element. The engagement of the alignment verification device with the prosthesis is adapted to permit a sighting element of an image obtaining device to be aligned with the alignment orifice and the visual indicator element so that an

image obtaining device is aligned with the prosthesis in a known orientation. The spinal disc prosthesis incorporates an angle. The system further comprising an orientable image obtaining device including a sighting element for aiding in orienting the image obtaining device, the sighting device being aimable through the alignment orifice to the visual indicator element to provide a visual indication that the image obtaining device is oriented in a predetermined orientation with respect to the prosthesis. Zdeblick et al. further disclose a method for verifying the orientation of an image obtaining device with respect to an implanted prosthesis, comprising the steps of: providing an alignment verification device including a spacer element having proximal and distal portions and a prosthesis engaging element disposed on the distal portion; and an alignment guide surface affixed to the spacer element and defining an alignment orifice, the alignment orifice being spaced apart from the prosthesis engaging element; engaging the alignment verification device to the implanted prosthesis, the prosthesis having an engaging element and a visual indicator element, the engaging element configured to releasably engage the prosthesis engaging element of the alignment verification device so that, upon engagement, the alignment orifice is spaced apart from the visual indicator element; orienting the image obtaining device so that a sighting element on the image obtaining device is aimed through the alignment orifice to the visual indicator element to provide a visual indication that a predetermined orientation between the image obtaining device and the prosthesis has been achieved.

Method Claim 19

Taking the method claim first, the rejection posits without support that Zdeblick discloses the step of "orienting the image obtaining device so that a sighting element on the image obtaining device is aimed through the alignment orifice to the visual indicator element to provide a visual indication that a predetermined orientation between the image obtaining device and the prosthesis has been achieved." There is no support whatsoever for this rejection – there are no citations to portions of the Zdeblick specification; no references to the Zdeblick figures; and no description of how a person of ordinary skill would find this element in Zdeblick. There is a very good reason for this lack of support in the rejection – Zdeblick never discloses teaches or suggests it.

First, Zdeblick deals with a very different type of prosthesis that does not give rise to the kinds of alignment issues that are addresses by the presently claimed invention. Zdeblick addresses problems involved with the insertion of cylindrical vertebral cages that are installed lengthwise. *See*, column 4, lines 31-34, and the substantial discussion in the Background at

column 1, line 54 to column 3, line 13 (beginning with: "one of the more prevalent designs takes the form of a cylindrical implant"). The implants are generally inserted by drilling and/or reaming a cylindrical space through disc and/or bone, and inserting the cylinder lengthwise into the drilled/reamed space. *See*, column 2, lines 57-67 for the prior art approach, and, for example, figures 8a through 8d of Zdeblick. This approach does not give rise to the rotational alignment problems within the spinal column that the claimed invention addresses – cylindrical implants are simply pushed or threaded into cylindrical holes.

Turning now more directly to the term from claim 19 – it is clear that Zdeblick does not need this step, and it is even more clear that Zdeblick does not disclose it. Again, this claim element recites:

> orienting the image obtaining device so that a sighting element on the image obtaining device is aimed through the alignment orifice to the visual indicator element to provide a visual indication that a predetermined orientation between the image obtaining device and the prosthesis has been achieved

Zdeblick discusses imaging at exactly 3 places in its specification. In each of those 3 places, there is no discussion of orienting the image obtaining device, no discussion of a sighting element on the image obtaining device, and no discussion of the sighting element being aimed through an orifice to a visual indicator on the prosthesis (in fact, the prosthesis is not even present on the 3 occasions that imaging is discussed).

The first of the three places that Zdeblick mentions imaging is with respect to the step of deploying a distractor:

> It is therefore important that the distractor tips 169 be properly located, which can be accurately confirmed with fluoroscopy. [Column 11, lines 65-67.]

The second of the three places that Zdeblick mentions imaging is with respect to the step of reaming out a cylinder for placement of the cylindrical implant:

> The depth of reaming necessary, and consequently the position of the depth stop 198, can be determined prior to this reaming step by review of fluoroscopic images.

> The reamer 197 is manually operated by way of a T-handle 199 to successively remove disc tissue and bone from the adjacent vertebral bodies to provide a prepared bore for the fusion implant. Preferably, several passes will be made with the reamer, after which the outer sleeve will be examined visually and fluoroscopically to verify that it remains fully seated within the disc space. In addition, the reaming should be observed under C-arm imaging to prevent reaming into the spinal canal. [Column 14, lines 28-40.]

The third of the three places that Zdeblick mentions imaging is with respect to the step of preparing a second site on the patient's left side (cylindrical implants are generally inserted in pairs) for placement of the cylindrical implant:

> Once the position of the outer sleeve and fingers 173 is confirmed using fluoroscopy, the remaining steps for preparing the vertebral bodies to receive the fusion implant are repeated at the left location ML. [Column 15, lines 9-12.]

Zdeblick uses imaging to distract and ream, and never mentions in any way using imaging to confirm the placement of the implant at all – let alone the need to align it to begin with – and much further, Zdeblick never mentions using a sighting element to establish the alignment of the imaging device with respect to a visual indicator element on the prosthesis as recited in claim 19.

In sum: this claim element is lacking entirely in Zdeblick and the Examiner implicitly understands this as the Examiner cites to no part of Zdeblick as disclosing it. There being no *prima facie* anticipation, claim 19, as well as the claims that depend therefrom, are patentable of Zdeblick.

System Claim 7

Turning now to claim 7, this claim recites a configuration of an alignment verification device and spinal disc prosthesis which, when connected, "is adapted to permit a sighting element of an image obtaining device to be aligned with the alignment orifice and the visual indicator element so that an image obtaining device is aligned with the prosthesis in a known orientation."

As an initial matter, the cylindrical fusion device of Zdeblick is not a spinal disc prosthesis, it is a fusion cage that does not replace a disc – it is also not shaped like a disc. The art recognizes that Zdeblick's fusion device is not a spinal disc prosthesis.

Further, the fusion device of Zdeblick has no visual indicator element, and the Examiner does not even attempt to cite to one.

Still further, it is impossible for the device of Zdeblick to meet the recitation quoted above as it is not adapted to permit the recited sighting, but instead blocks it. The Examiner refers only to Figure 21 of Zdeblick, and states that the laparoscopic port 180 provides the alignment orifice, and that the laparoscope outer sleeve 170/171 is an alignment guide surface. The Examiner further states that impactor 245, which drives the dowel shaped implant into place, is the "spacer" recited. Here is the problem – the impactor 245 fills the laparoscopic port 180 – meaning that the orifice, as cited by the Examiner, is completely blocked by the spacer, as cited by the Examiner. The system cannot be adapted for the recited sighting because the place where the sighting is to take place is completely and totally blocked from any kind of sighting.

One might suggest that the "spacer" could be pulled out of the orifice for the purpose of sighting – but then the system element would still not be met because now there would be no spacer having an alignment guide surface with an orifice affixed thereto – that is, the alignment verification device recited in the claim would not be present. See, *Net MoneyIn, Inc. v. Verisign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008) ("the prior art reference--in order to anticipate under 35 U.S.C. § 102--must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements 'arranged as in the claim.' *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983).")

These claim elements not being met – there can be no anticipation of claim 7 and claim 7 and the claims that depend from it are in condition for allowance.

CONCLUSION

The pending claims are in condition for allowance. Applicants request that the Examiner telephone the undersigned in the event that such communication is deemed to expedite prosecution of this matter.

In the event that a petition for an extension of time is required to be submitted at this time, Applicant hereby petitions under 37 CFR 1.136(a) for an extension of time for as many months as are required to ensure that the above-identified application does not become abandoned.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 141449, under Order No. 101896-31.

Respectfully submitted,

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